CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

SETHOXYDIM

Chemical Code # 2177, Tolerance # 412
SB 950 # 299

Jan. 8, 1998
Revised 11/23/98

I. DATA GAP STATUS

Chronic toxicity, rat:	No data gap, no adverse effect
Chronic toxicity, dog:	No data gap, no adverse effect
Oncogenicity, rat:	No data gap, no adverse effect
Oncogenicity, mouse:	No data gap, no adverse effect
Reproduction, rat:	No data gap, no adverse effect
Teratology, rat:	No data gap, possible adverse effect
Teratology, rabbit:	No data gap, no adverse effect
Gene mutation:	No data gap, no adverse effect
Chromosome effects:	No data gap, no adverse effect
DNA damage:	No data gap, no adverse effect
Neurotoxicity:	Not required at this time

Toxicology one-liners are attached.

All record numbers for the above study types through 160872 (Document No. 412-172) were examined. This includes all relevant studies indexed by DPR as of 11/23/98. Many of the older records for this active ingredient are of the document series > 900,000.

In the 1-liners below:

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

COMBINED, RAT

412 -167 142526 Mellert, W., K. Deckardt, B. Kittel and B. Hildebrand, “Sethoxydim - Combined chronic toxicity and carcinogenicity study in Wistar rats, administration in the diet for 24 months”. BASF Aktiengesellschaft, Ludwigshafen, 10/17/95. BASF Project No. 85S0155/92028. Sethoxydim, purity 96.8%, was administered in diet at 300, 1000, 3000 ppm for 24 months to 50 (oncogenicity study group) and 10 (satellite group) Wistar rats/sex/group. The mean achieved dose for the nominal 300 ppm group was estimated to be 264 ppm. Minor body weight changes in mid-dose males and in high dose males and females appeared to be treatment-related. The primary target organ was liver, with a NOEL of 300 ppm (12 mg/kg/day in males, the more sensitive sex), based on hepatic centrilobular hypertrophy. Elevated creatinine and bilirubin levels, confined mainly to high dose rats, were occasionally seen at the LOEL, but were less certain to be treatment effects. The study was originally classified as unacceptable due to lack of full stability data. Supplemental data in Record No. 160872 address this issue and allow an upgrade to **acceptable status. No adverse effects were identified. (Kishiyama and Aldous, 1/8/98; re-examination by Aldous, 11/23/98).

412 -171 160872 Hastings, C., “Sethoxydim chronic rat study: response to California EPA question on dietary stability”, Addendum to Document # 412 -167, Record # 142526: ”Sethoxydim - Combined chronic toxicity and carcinogenicity study in Wistar rats, administration in the diet for 24 months”. Final Report Dates: October 17, 1995 (of original record): March 10, 1998 (of supplement). Page 1920 of the original submission provided a table stated to address stability of dietary admixtures of sethoxydim, however the conditions of storage were not evident from the table. The new submission provides this information. In particular, samples #7 and #8 represent stability at 8 days after preparation at room temperature for 300 ppm and 2700 ppm, respectively. Assayed concentrations were 94.3% and 98.5% of respective freshly prepared samples. These data suffice to upgrade the study to acceptable status. Aldous, 11/23/98.

412-093 115073 Burdock, G. A. (Study Director). "104-week chronic dietary study of NP-55 (Sethoxydim) in rats, final report (Part I)". Hazleton Laboratories, Project No. 886-102, Dec., 1981. Sethoxydim, 96.1% and 94.8%, Lot Nos. PN 1-2 and PN-3, was administered to Fischer 344 rats in the diet for 2 years at 0, 40, 120 or 360 ppm, 55/sex/group. Five/sex/group were sacrificed at 12 months. NOEL = 360 ppm (HDT). Summary data only. No adverse effects were indicated. Unacceptable. The 1985 CDFA review (see immediately below) indicated that the report needed individual data and justification of dose selection. Since there are long-term rat studies using more defensible dose ranges, there is no reason to seek to upgrade this study. C. Aldous, 8/14/85 and 10/23/97.

412-008 903699 and 412-002 903698 These were the record numbers containing a less complete version of Record No. 115073, above; reviewed 8/14/85 by Aldous.

other remarkable changes for in-life parameters nor in histopathology, hence no “adverse effects”. Study is not acceptable nor upgradeable (primarily due to lack of adequate challenge to high dose rats). No further data are requested from this study. Aldous, 10/24/97.

412-100 115094 Nishibe, T. *et al.* “Subacute Feeding Study of NP-55 in Rats”; Nippon Soda Co., Ltd., 10/18/78. Sethoxydim (95.9% purity) was admixed in the feed at concentrations of 0, 33, 100, 300, 900 and 2700 ppm and fed to 20 Wistar rats/sex/group for 14 weeks. Body weight gain was reduced 17% and 14% for high dose males and females, respectively. Total cholesterol, bilirubin levels, and liver weights were elevated at 900 to 2700 ppm. Swollen liver cells were increased in dose-related fashion in 900 ppm to 2700 ppm males. High dose females were similarly affected, but at lower incidence. Apparent NOEL was 300 ppm, estimated to be about 20 and 21 mg/kg/day in males and females, respectively. No DPR worksheet (Aldous, 12/4/97).

412-008 037057 (text) and 412-001 (same record number, contains tables). These records report respective portions of study 412-100 115094, above.

412-095 115078 Commentary submitted by BASF in support of Record Nos. 115073 and 115075, above. No DPR review is relevant. Aldous, 10/24/97.

COMBINED (ONCOGENICITY AND CHRONIC), MOUSE

412-097 115086 Complete report, corresponding to partial data in Document #’s 412-002 and -008, Record #’s 903697 and 903696. Nishibi, T., H. Takaori, and S. Satoh, “Chronic feeding study combined with oncogenicity study of NP-55 in mice”, Nisso Institute for Life Science, Final Report Date: Sept. 1981 (original report). Document No. 412-097 was submitted June 2, 1992. BASF Study # 81/9014. Sethoxydim, lot No. PN-1-2, 95.4%, was administered to BDF1 mice in the diet for 2 years at 0, 40, 120, 360 or 1080 ppm, 60/sex/treated group, 90/sex/control group. An additional 10/sex/group were sacrificed at 1 yr for interim histopathology evaluation. NOEL = 120 ppm. Primary findings were increased liver weight and fatty degeneration of liver in both sexes at 1080 ppm: the latter also in 360 ppm males. Males at 1080 ppm had a body weight decrease despite increased food consumption, and also increased SGOT and SGPT values. No treatment-related oncogenicity. No adverse effect. Study was initially not accepted due to inadequate information on diet analysis and lack of individual gross and microscopic pathology data. Record #115086 provided the requested data, and the study is now **acceptable. The 1997 review provides tables showing essential findings. C. Aldous, 8/13/85 and 10/28/97.

412-098 115087. Takeori, H., “Phase 3 Summary of MRID 100527: Sethoxydim - chronic feeding study combined with oncogenicity study of NP-55 in mice”, 5/22/90. (A summary of Record No. 115086, and a filled-out checklist of FIFRA requirements met by that record. Evidently provided by Nippon Soda Company to supplement that record). No worksheet. (Aldous, 10/28/97).

All long-term rat dietary studies are found under “Combined, Rat”, above.

CHRONIC TOXICITY, DOG

412-096 115084 Spicer, J. F., “One year dietary toxicity study in dogs”, IRDC, May 1984, BASF #84/161. NP-55 (sethoxydim), Lot No. KK-1240, 96.86% purity, was administered to beagle dogs in the diet at 0, 300, 600 or 3600 ppm for 1 year, 6/sex/group, in a standard chronic study. Achieved doses were 0, 8.86, 17.5 and 110 mg/kg/day for males and 0, 9.41, 19.9 and 129 mg/kg/day for females. A functional NOEL = 300 ppm, with plausibly treatment-related findings of no obvious health significance at 300 ppm in livers of males: a “ground glass” appearance of hepatocellular cytoplasm was dose-related at and above 300 ppm in males and 600 ppm in females. Alkaline phosphatase was elevated in 600 ppm males. Liver-related findings at 3600 ppm, usually in both sexes, included the above findings, plus elevated liver weight, elevated alanine aminotransferase, and reduced calcium, albumin, and cholesterol. Hemosiderosis was unaffected in females, but appeared elevated in spleens of males, based on the original study report. This was not confirmed upon blind re-evaluation of the slides (see DPR review of blinded histopathologic re-evaluation in Record No. 115082). There was a dose-related decrement in RBC parameters (RBC count, HCT, and Hb) at 600-3600 ppm in males, however no clinical signs of anemia were evident at any dose level. **Acceptable, with no adverse effects. Aldous, 11/18/97.

412-043 and 412-044 045207 and 045208 (duplicate of 412-096 115084, above).

412-095 115080 Summary of 412-096 115084, evidently prepared for EPA (no DPR review).

412-095 115082 Payne, B. J. and C. D. King, “A blinded histopathologic review of spleen and bone marrow”, Addendum to Document #: 412-096, Record #: 115084. Consulting firm: Xenos (North Branch, NJ). Final Report Date of supplement: 4/26/88. BASF Study # 88/5028. The reviewing pathologist, Dr. Payne, reviewed all slides of both sexes and all treatment groups reported in Record # 115084 in “blind” fashion for the following categories: spleen (H&E), spleen (iron stain), and sternal bone marrow (H&E). The LEL for increased splenic hemosiderosis was 3600 ppm. Study results do not demonstrate a treatment effect on splenic erythropoiesis. There was a general decrease in erythroid colonies in sternal bone marrow at 600 to 3600 ppm. This does not appear to reflect a meaningful decrement in RBC production, since RBC counts, HCT, and Hb were gradually increasing in all groups over the course of the study. In summary, the hematological data presented in the review of the original study submission showed an equivocal reduction of RBC parameters compared to concurrent controls, but within historical control range. Based on the “blind” re-evaluations of hematopoietic tissue slides in Record No. 115082, there is no supporting evidence that hematology changes reflect functionally important effects below 3600 ppm. Aldous, 11/20/97.

412-008 903689 (text) and 412-001 903690 (tables and individual histopathology data) This is

REPRODUCTION, RAT

412-099 115093, "Two generation reproduction study of NP-55 in rats", (Marroquin, F. M., IRDC, BASF Document No. 84/0068, 12/12/83). Sethoxydim (NP-55), purity 96.86%, was administered in diet at 0, 150, 600 or 3000 ppm to 13 male and 26 female Charles River CD® rats/group in a two generation reproduction study, with 2 littering periods/generation. This study pre-dated current guidelines, however the data are sufficiently interpretable to constitute an acceptable study. Reproductive effects NOEL = 600 ppm (decrement in pup body weights). Parental NOEL = 150 ppm (fatty vacuolation in adrenal cortex). Body weights were slightly reduced in 3000 ppm adults, especially in females. Liver weights were slightly elevated in 3000 ppm males, and a general increase in the degree of fatty and hydropic vacuolar change in liver was suggestive of a mild treatment effect. **Acceptable, with no adverse effects. Kishiyama and Aldous, 12/19/97.

412-128 138642 Grossi, I. M. “Determination of homogeneity and stability of NP-55 (Sethoxydim) in dietary mixtures”, IRDC, 9/2/94. (A retrospective analysis, submitted in support of 2-generation study, 412-099 115093, above). Reg. Doc. # BASF 94/5111. Data indicate that sethoxydim is stable in diet over at least 10 days “under laboratory conditions”, and that content and homogeneity of sethoxydim in diets are within specifications. It is unclear how to interpret the data on the sethoxydim degradation product, M-SO, as discussed in the review. Aldous, 12/18/97.

412-099 115136 Registrant’s summary of results of 099 115093. No DPR worksheet.

412-008 903695 "Two-Generation Reproduction Study of NP-55 (Sethoxydim) in Rats" (IRDC Report No. 449-001, 11-27-81) Sethoxydim, 95%, Lot No. PN-2-1, was given to COBS-CD rats in their feed for a 2 generation reproduction study at 0, 40, 120 or 360 ppm, 12 males and 24 females per group. Four months into the study an additional control group and 1080 ppm treated group were added, after 4 weeks the treated level was raised to 2160 ppm, then 3240 ppm after another 4 weeks. Toxicity was suggested at 3240 ppm by decreased body weight in adults (not statistically significant at most time intervals), slight decrease in weanling weights (not significant), increase in relative male liver weights and decrease in relative female adrenal weights. No adverse effects. UNACCEPTABLE. The study lacks individual data and dose selection is too low to be useful. C. Aldous, 8/16/85 (1-liner modified 12/19/97).

412-002 903694. Summary of results tables for 903695. (Kishiyama, 3/4/94).

TERATOLOGY, RAT

****412-118 128265** Ponnock, K. S. "A developmental toxicity study in rats with sethoxydim", Pharmaco LSR, Inc., Project No. 92-3826, BASF Reg. Doc. No. 93/5166, 12/15/93). Sethoxydim, purity 96.8%, was administered by gavage at 0, 50, 180, and 650 mg/kg/day to 24

associated with absent sacral and/or caudal vertebrae, reduced mean fetal body weight (significant, $p < 0.01$), and increases (often marked) in ossification delays in several vertebral and sternebral locations. Findings of absent sacral and/or caudal vertebrae constitute **a possible adverse effect**. Study is **acceptable.** Kishiyama and Aldous, 12/19/97.

412-108 121520 Range-Finding study for 128265 (includes an adverse effect disclosure, strictly for salivation at all doses, noted also in the primary report). This study is also included within the main study report (128265). No worksheet. Kishiyama and Aldous, 12/10/97.

412-098 115090 (Portions of this report were reviewed earlier as Record #'s 903692 and 031121). Nishibe, T. and K. Gotoh, "Phase 3 reformat of MRID 45863: Teratology of Sethoxydim to rats", Nisso Institute for Life Science. Date of original report was 4/17/80: date of "reformat" was 4/27/90. Original report was designated # RD-8050; "reformat" was labeled Reg. Doc. #BASF 90/6100. The "reformat" was the first submission to CDFA or DPR which provided individual data. Sethoxydim, 94.0%, Lot No. PN-2-1, was administered to presumed pregnant Sprague Dawley rats, 24/group, at 0 (1% CMC, 0.1% Tween 80), 40, 100 or 250 mg/kg/day on days 7-17 of gestation. Aspirin was used as a positive control at 200 mg/kg/day, producing many abnormalities, including craniorachischisis and wavy ribs, among a variety of skeletal anomalies. Developmental NOEL = 40 mg/kg/day (bilobate thoracic vertebrae as a possible treatment effect). Maternal NOEL = 40 mg/kg/day (slight body weight decrement). Maternal findings at 250 mg/kg/day included elevated liver weight and reduced adrenal gland weights. Developmental findings at 250 mg/kg/day included delayed development of proximal phalanges. There was also a weak indication of increased incidence of 14th rudimentary ribs at 250 mg/kg/day. These findings do not indicate an adverse effect. The 1985 CDFA review considered the study as **not acceptable**, since the report was not complete. The present record is the complete report. This study lacks several features of more modern studies, such as QA oversight and analyses of dosing suspensions. The more recent rat teratology study, Record No. 128265, meets current guidelines and provides a more rigorous dosage range, hence is more relevant for hazard assessment than this study. There is thus no advantage in reconsidering this study for acceptability. Aldous, 1/8/98.

412-008 903692 Text portion of Record No. 115090, above.

412-002 031121 Summary table portion of Record No. 115090, above.

412-098 115088. Retrospective analysis of dosing mixture for test article homogeneity (top, middle and bottom were within 5%) and stability (up to 31 days) for 412-098 115090, above. Homogeneity and stability (31 days at refrigerator temperature) were satisfactory. No worksheet was prepared, since the cited study has been superseded by an acceptable study with a more challenging dosing regimen. (Kishiyama and Aldous, 12/10/97).

412-098 115089 "Phase 3 summary of MRID 45863 and related BASF Doc #90/5020" [summary prepared by K. Gotoh]. (Relates to 412-098 115090, above). Summary was evidently

Supplemental. The reason for this study is not clear since this metabolite is not one of the common rat metabolites. C. Aldous, 8/16/85.

TERATOLOGY, RABBIT

412-117 128264 Ponnock, K. S., "A developmental toxicity study in rabbits with Sethoxydim", Bio/dynamics, Inc., 11/22/93. Project No. 92-3827. Sethoxydim, purity 96.8%, was administered by gastric intubation at 0, 80, 160, 320, or 400 mg/kg/day to 15 mated NZW rabbits/group during gestation days 6-18. Maternal NOEL = 320 mg/kg/day; food consumption was significantly reduced and there was one abortion (possibly treatment-related) at 400 mg/kg/day. Developmental NOEL = 400 mg/kg/day. **Acceptable; no adverse effects. Kishiyama and Aldous, 11/21/97.

412-008 903693 Rodwell, D. E. and P. E. Steed, "Teratology Study in Rabbits - NP-55 (in support of Poast)" (IRDC Report No. 449-003, 5/23/80) Sethoxydim, 95%, was administered by gavage to presumed pregnant New Zealand White rabbits at 0 (0.5% CMC), 40, 160 or 480 mg/kg/day on days 6-28 of gestation. Only 2 litters were examined at 480 mg/kg/day due to deaths, abortions and resorptions. No maternal toxicity, fetotoxicity or teratogenicity at 160 or 40 mg/kg/day. No adverse effect. UNACCEPTABLE. No useable treatment group in maternally toxic range, only 2 dose groups can be evaluated. C. Aldous, 8/14/85.

412-098 115091. Phase 3 Reformat of MRID 45864 (008 903693 and 002 31122), but with Appendices (QA statement, protocol, historical control and personnel). No worksheet. Study status remains unacceptable. No more data needed (Kishiyama and Aldous, 12/11/97).

412-098 115092. Phase 3 Summary of MRID 45864 (008 903693). Addresses acceptability issues with respect to U.S. EPA guidelines. No worksheet. Aldous, 12/11/97.

GENE MUTATION

**412-101 115099 Nishibe, T., "Sethoxydim - reverse mutation study on bacteria (Ames Test)", Nippon Soda Co., Ltd., 8/24/90. BASF Reg. Doc. # 90/0380. Sethoxydim, purity 95.45%, was evaluated for mutagenicity using *Salmonella typhimurium* (TA100, TA1535, TA98 and TA1537), with and without metabolic activation (S9 mix) at concentrations of 0 (DMSO), 312.5, 625, 1250, 2500 and 5000 µg/ml, with a 20-minute preincubation before plating. Bacterial growth was reduced at the high dose. Numbers of revertant colonies did not increase with Sethoxydim treatments in either of the two trials. Acceptable. (Kishiyama and Aldous, 1/8/98)

008 903700 "Mutagenicity Testing on NP-55 (Sethoxydim) in Microbial Systems (Reverse Mutation with *Escherichia coli)*" (Institute of Environmental Toxicology, Tokyo, Japan, 11-21-79) Sethoxydim, 94.8%, was assayed with *S. typhimurium* strains TA1538, TA98, TA100, TA1535

with 1% Tween 80), 100, 310, 496, 1080 or 2500 mg/kg, 5 females/group. *S. typhimurium* strain G46 was injected i.p. the last day of dosing for a host mediated assay. No adverse effect. UNACCEPTABLE. No analysis of dosing solution, not a standard protocol. C. Aldous, 8-15-85.

002 31123. Summary of results tables for 903701. (Kishiyama, 3/4/94)

CHROMOSOME EFFECTS

**412-101 115101 Cimino, M. C., "Mutagenicity evaluation of NP-55 in the Chinese hamster bone marrow cytogenetic assay", Litton Bionetics, Inc., Dec. 1981. LBI Project No. 22135. NP-55 (sethoxydim), purity 98.1%, was administered by gavage in concurrent acute (one time treatment) and repeat-dose (once daily for 5 days) series at concentrations of 0 (DMSO), 0.5, 1.67 and 5.0 g/kg to 4 Chinese hamsters/sex/group/sacrifice time. Bone marrow preparations of hamsters were evaluated for chromosomal aberrations at 6, 24, and 48 hours after the final treatment for the acute series and at 6 hours for the repeat-dose series, respectively. Of the 4/sex in the repeat-dose 5.0 g/kg group, only 2 females survived. Other treatment regimens were tolerated. Sethoxydim treatments indicated no cytogenetic effects under study conditions. Study is acceptable with deficiencies as noted in the review. (Kishiyama and Aldous, 12/19/97).

412-101 115102, Phase 3 Summary of MRID 41475206 (DPR record 115101, above). The summary identifies Lot no. PN-7 (used in the cited record), as TGAI of purity 98.1%. The study was compared against U.S. EPA acceptance criteria, and the only noted deficiency was the lack of 5 animals/sex per experimental group. The author (H. Takaori) considers 4 animals/sex to be sufficient to provide statistical rigor for the study. The DPR review did not invalidate the study for this deficiency. Kishiyama and Aldous, 12/17/97.

DNA DAMAGE

**412-101 115098 McKeon, M. E., "Genotoxicity test on sethoxydim in the assay for unscheduled DNA synthesis in rat liver primary cell cultures", Hazleton Laboratories America, Inc., Kensington, MD, 4/25/91. HLA Study No. 12526-0-447. BASF Reg. Doc. #90/10235. Sethoxydim, purity 95.45%, at concentrations of 0 (DMSO), 10.1, 25.3, 50.7, 101, 253, or 507 µg/ml, was evaluated for UDS by autoradiography. Treatment time was 19.1 hours. Triplicate coverslips were scored with 50 cells per coverslip per concentration. Test material was insoluble in media above 101 µg/ml. Sethoxydim was negative under study conditions. Acceptable, with no adverse effects. Kishiyama and Aldous, 1/8/98.

008 34797 "Mutagenicity Testing on NP-55 in Microbial Systems (in support of Poast) - Rec-Assay Test with *B. Subtilis*" (Institute of Environmental Toxicology, Tokyo, Japan, 11-21-79) Sethoxydim was assayed for DNA damage with *B. subtilis* strains H17 and M45 by the filter paper disk method at 0 (DMSO), 1, 5, 10, 25, 50 or 100 percent (v/v). There was no testing in

Me-MSO, purity 97.2%, was tested in standard plate assays with *Salmonella typhimurium* (TA100, TA1535, TA98, TA1538, and TA1537) and *Escherichia coli* (WP2 uvrA). All tests used levels of 0, 50, 100, 500, 1000, 5000, 10000, 50000 or 100000 µg/plate, with and without metabolic activation (S9 Mix). Bacterial growth was inhibited at 50000 or 100000 µg/plate in all tests, and test article precipitation was observed in S9-activated assays at the same levels. Test article did not increase the number of revertant colonies under study conditions, whereas positive controls were functional. Unacceptable (two replicates only and no repeat test). No adverse effects indicated for this metabolite. Aldous, 1/7/98.

412-101 115100 Nishibe, T., "Reverse mutation study on bacteria (Ames test) for Sethoxydim metabolite - 5-0H-M-SO_2", Nippon Soda Co., Ltd., Japan, 8/24/90, Reg. Doc. No BASF: 90/0381. Sethoxydim metabolite, 5-0H-M-SO_2, purity 98.7%, was tested at 0 (DMSO), 313, 625, 1250, 2500 and 5000 µg/ml with *Salmonella typhimurium* strains (TA100, TA1535, TA98 and TA1537) with and without metabolic activation (S9 Mix), with a 20-minute preincubation before plating, triplicate plates. The numbers of revertant colonies did not increase with sethoxydim treatments under the conditions of this study. Results were similar in a repeat test. Positive controls were functional. Since the test article is a metabolite of sethoxydim, the test information is considered supplemental. (Kishiyama and Aldous, 1/8/98)

412-083 088037 Cifone, M. A., "Mutagenicity test on 5-OH-MSO_2 in the rat liver primary hepatocyte unscheduled DNA synthesis assay", Hazleton Laboratories America, Inc., Kensington, MD, 12/4/89, BASF Doc. No. 89/0466. 5-OH-MSO_2, purity 98.9%, was tested at concentrations of 0, 500, 1000, 2000, 3000, 4000, and 5000 µg/ml for UDS on cultured rat hepatocytes. Treatment time was 18.2 hours. 5-OH-MSO_2 levels under study conditions did not induce UDS. Test is valid, but information is considered supplemental, since test article was a metabolite rather than the active ingredient. Kishiyama and Aldous, 1/7/98.

101 115105. Phase 3 Summary of MRID 41421301 (DPR Record # 088037). Prepared by J. O'Reilly. No DPR worksheet. (Aldous, 1/8/98).

412-017 1832 "Cytogenetic Investigations in Chinese Hamsters after a Single Oral Administration of 5-OH-MSO_2 (Poast Herbicide)" (BASF, Report No. 10M0179/8316, 1-30-84) 5-OH-MSO_2, a metabolite, was given to Chinese hamsters in a single oral, gavage dose at levels of 0 (0.5% CMC), 1000, 3000, or 10,000 mg/kg. Marrow samples from the femur were taken 6, 24, and 48 hours after dosing and analyzed for chromosome aberrations. There was no increase in structural chromosomal aberrations. No adverse effect. Supplemental. This study gives potentially useful information about one metabolite of the technical material. Intrinsic mutagenicity of the metabolite cannot be assessed because the degree of absorption is not reported. C. Aldous, 8-16-85.

412-101 115103, Phase 3 Summary of MRID 130710 (DPR record # 1832). Prepared by J. O'Reilly. The study was compared against U.S. EPA acceptance criteria, and the only noted deficiency was that the test article was not the active ingredient. No worksheet. (Kishiyama and

412-101 115104 Phase 3 Summary of MRID 155130 (017 1831). This addendum contains an undated GLP statement, plus “certification of availability of raw data” and “certification of accuracy of summary and adequacy of the study”, signed by C. A. Sanson on 5/22/90. This study bears a QA inspection statement by LBI, stating that this particular study was not inspected by QA while in process, but that QA evaluated studies of this type at least once every 3 months. No DPR worksheet, since the study is supplemental, as it did not test the a.i. (Kishiyama and Aldous, 12/17/97).

NEUROTOXICITY

Not required at this time.

OTHER RECORDS WHICH APPEAR IN THE LIBRARY PRINTOUT OF “SB-950" DATA BUT WHICH ARE NOT SETHOXYDIM DATA REPORTS, OR WHICH ARE SHORT-TERM STUDIES NOT REQUIRED UNDER SB-950

412-110 123952 A 1991 petition for a tolerance: no new studies. (Aldous, 12/18/97)

412-006 903674 A summary of studies available as of 1983. (Aldous, 12/18/97)

412-037 040578 A U.S. EPA data call in (1985). (Aldous, 12/18/97)

412-015 001828 Nishibe, T. *et al.*, “Subchronic feeding study of 5-OH-MSO_2 in rats”, Nisso Institute for Life Science, 10/31/83. This metabolite of sethoxydim was reported to have no evident toxicity up to the highest dose tested, 1080 ppm in diet over 13 weeks in a standard subchronic study. 412-015 001829 is the analysis of treated diet. No DPR worksheet at this time. (Aldous, 12/18/97)